

Edwards Is Enough!

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Western Australia

Meeting Name

Disclosure Statement of Financial Interest

Within the past 12 months, I or my spouse/partner have had a financial Interest /arrangement or affiliation with the organization(s) listed below

Affiliation/Financial Relationship

Company

Grant/ Research Support:

Medtronic Inc

Consulting Fees/Honoraria:

Edwards Lifesciences
(consultant & proctor)

Major Stock Shareholder/Equity Interest:

Royalty Income:

Ownership/Founder:

Salary:

Intellectual Property Rights:

Other Financial Benefit:

- My title is “Edwards is enough!!”
- Or is it “Edwards is better than CoreValve”...?
- What is “enough”??

My wish list

- True percutaneous insertion
- No need for general anesthesia
- Multiple valve sizes
- An easy sizing tool for annular size
- Smallest size possible <16 Fr
- Smooth outer surface to pass through aorta
- Easy transition over arch
- Easy transit through valve
- "Self seating"
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- Repositionable if needed
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Percutaneous Aortic Valve Replacement

Vascular Outcomes With a Fully Percutaneous Procedure

Stefan Toggweiler, MD,* Ronen Gurvitch, MBBS,* Jonathon Leipsic, MD,† David A. Wood, MD,*
Alexander B. Willson, MBBS,* Ronald K. Binder, MD,* Anson Cheung, MD,‡ Jian Ye, MD,‡
John G. Webb, MD*

Vancouver, British Columbia, Canada

Results

PAVR was performed in 137 consecutive patients. All but 1 patient underwent planned arteriotomy closure using a percutaneous pre-closure technique. Smaller sheaths, rigorous angiographic and computed tomographic screening and patient selection, and percutaneous vascular repair techniques were increasingly used over this period. From 2009 to 2010, major vascular complications decreased from 8% to 1% ($p = 0.06$), minor vascular complications decreased from 24% to 8% ($p < 0.01$), major bleeds fell from 14% to 1% ($p < 0.01$), and unplanned surgery decreased from 28% to 2% ($p < 0.01$). A minimal artery diameter smaller than the external sheath diameter, moderate or severe calcification, and peripheral vascular disease were associated with higher vascular complication rates.

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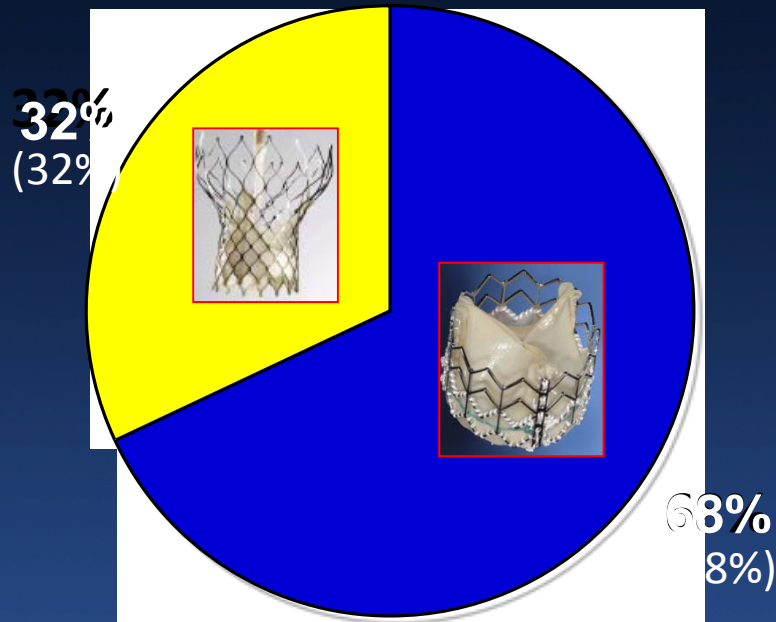


FRANCE 2



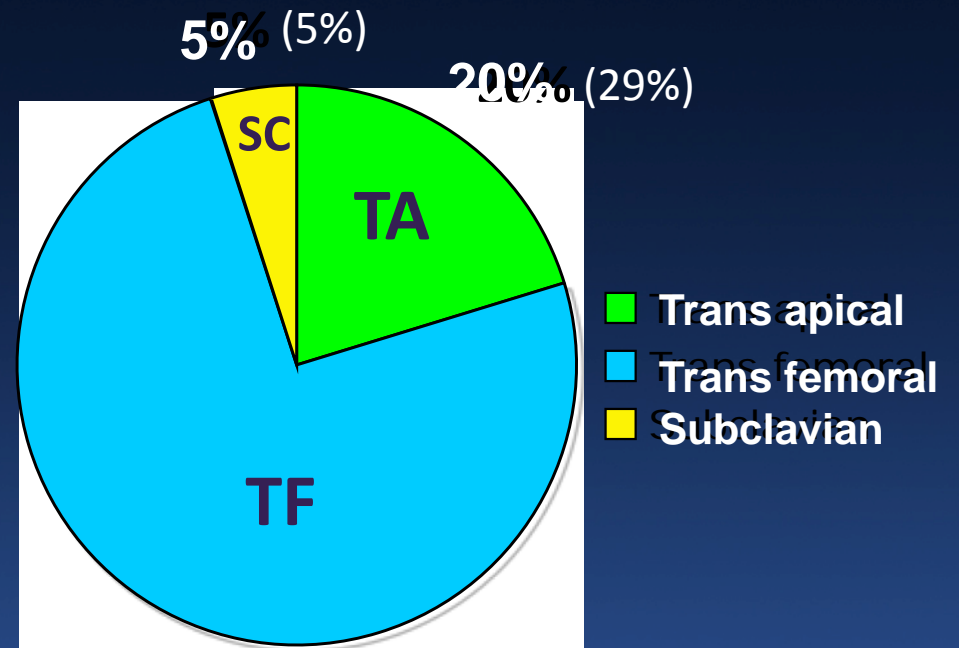
Valves and approaches used

Valves



- Edwards
- CoreValve

Approach

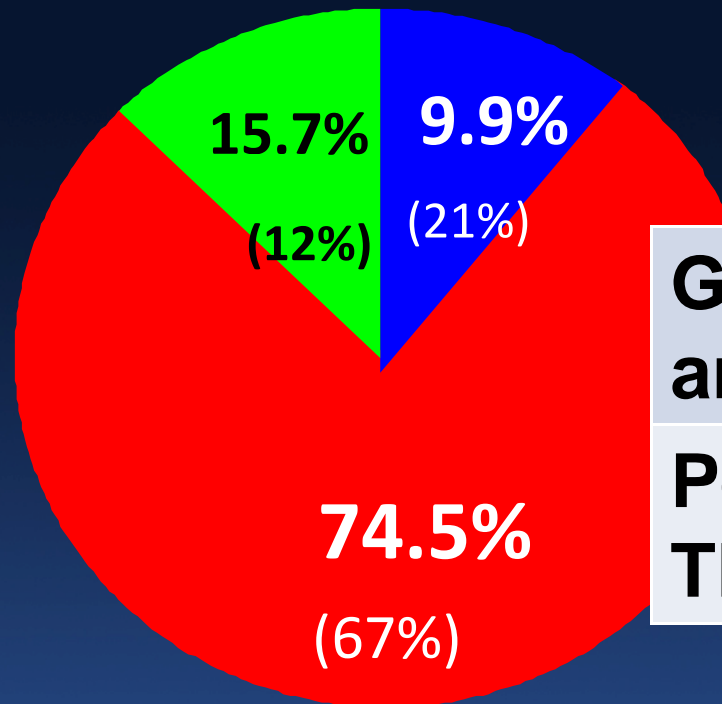


- Trans apical
- Trans femoral
- Subclavian



FRANCE 2

Procedural characteristics



- Operative room
- Cath-lab
- Hybrid room

General anesthesia, %	71.6 %
Per-procedure TEE, %	65.9 %

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Edwards NovaFlex+ 29mm TF : Q2, 2012 CE Mark

- SAPIEN XT valves with dimensions and associated annulus size ranges

23 mm



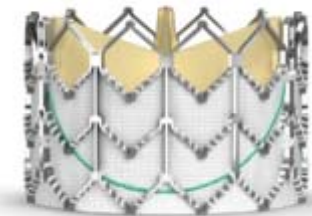
14.3 mm

26 mm

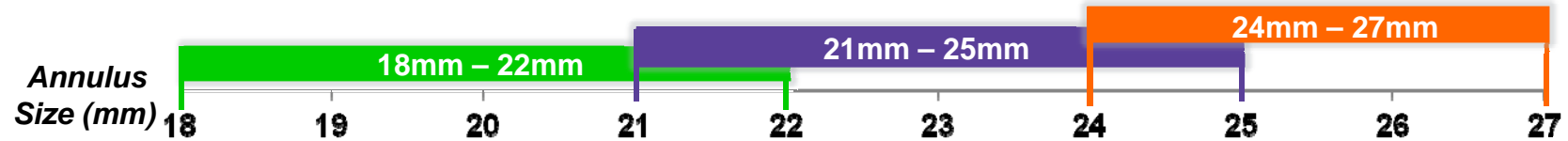


17.2 mm

29 mm



19.1 mm

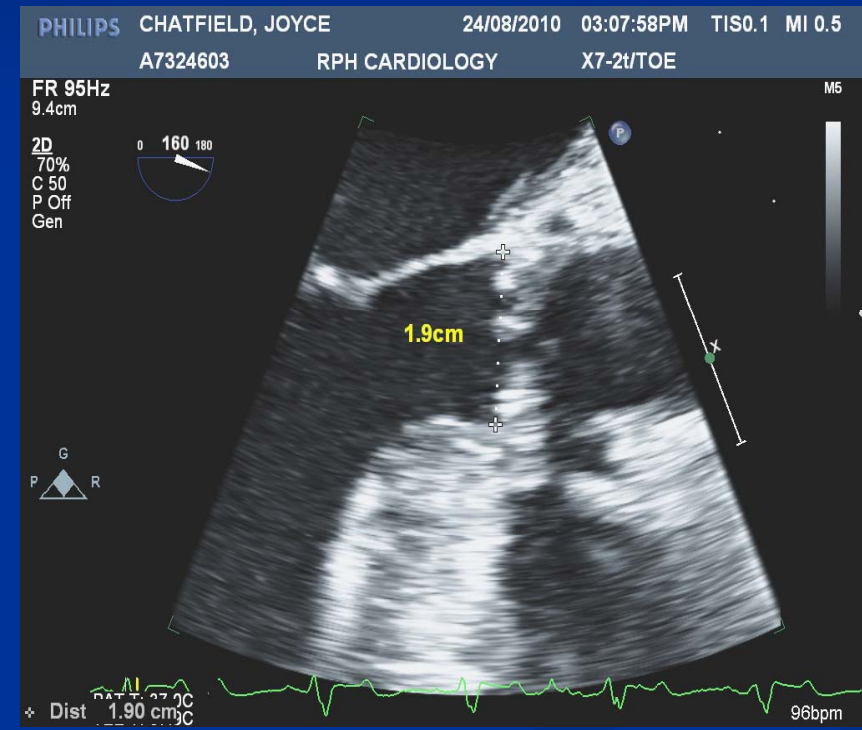


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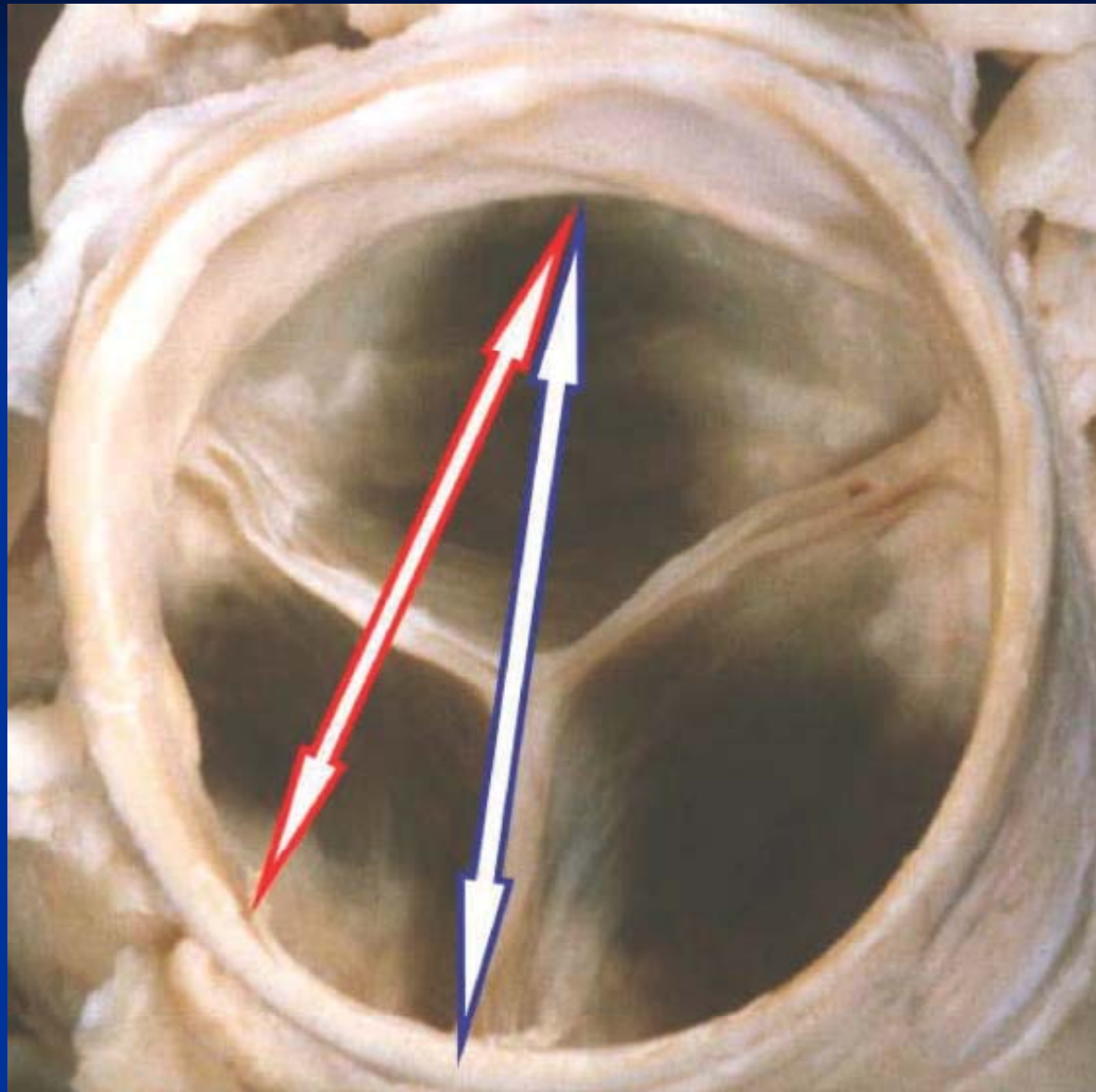


Aortic Annulus Measurement



TOE:

- Long Axis view
- See valve leaflets
- See the leaflet insertion / hinge



MSCT Assessment of Annulus

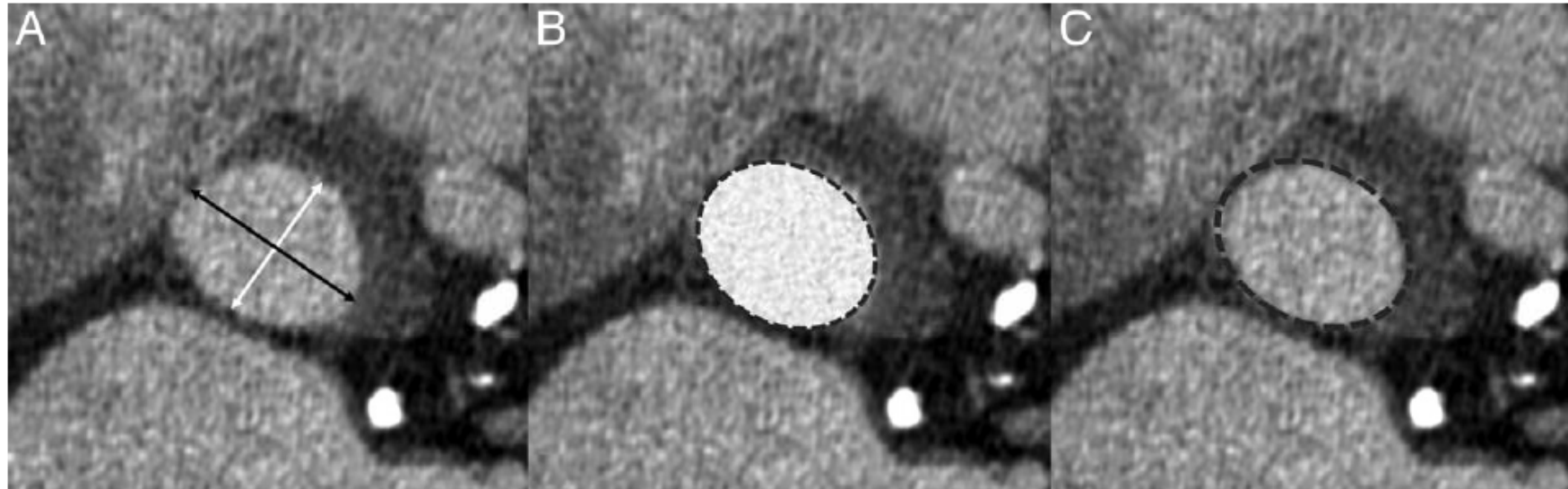


Figure 2 Three-Dimensional MDCT Aortic Annular Measurements

(A) Short and long diameters provide a mean annulus diameter and annular eccentricity. (B) Annular area. (C) Annular circumference.
MDCT = multidetector computed tomography.

- Mean Diameter as Average of Smallest & Largest Diameters
- Mean Diameter as Annular Circumference / π
- Mean Diameter as $\sqrt{(4 \times \text{Annular Area} / \pi)}$
- Annular Area
- Annular Circumference

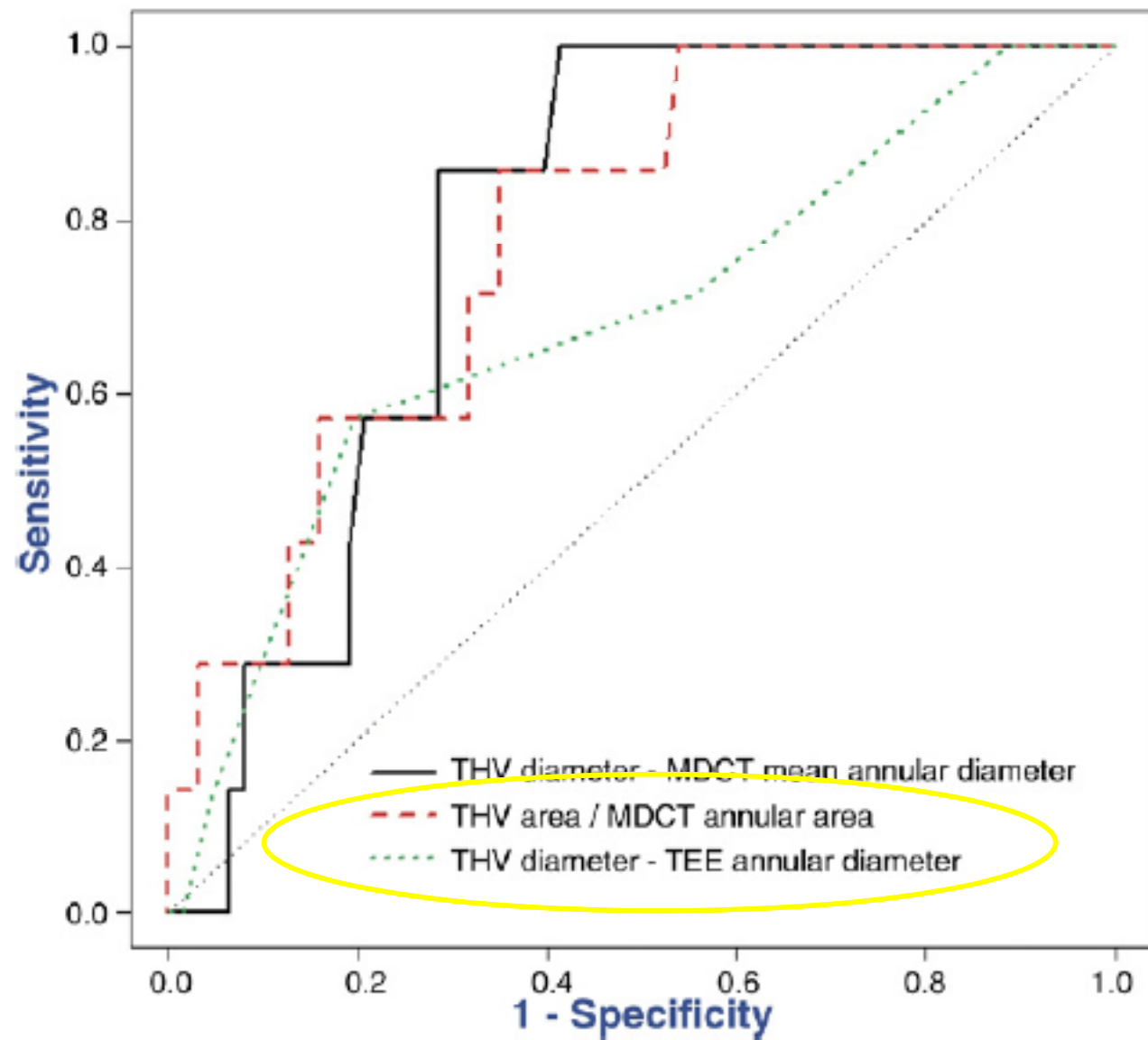


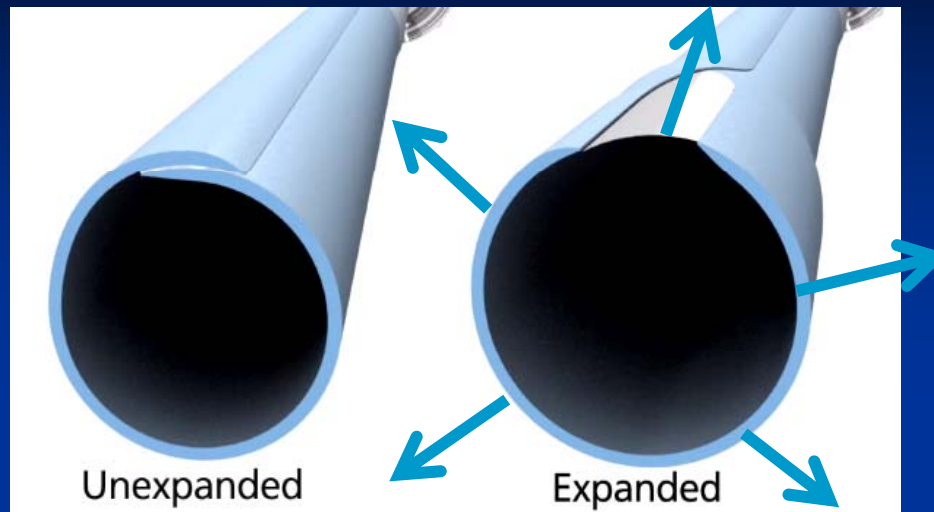
Figure 3

Area Under the Receiver-Operating Characteristic Curves for Prediction of PAR

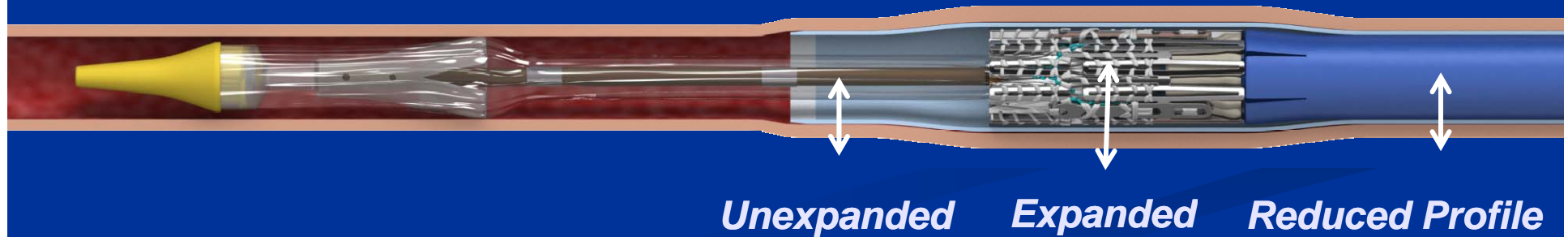
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The Edwards eSheath - 16Fr

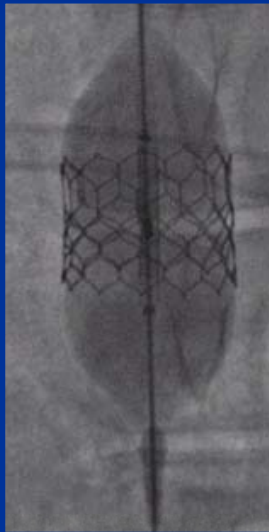


The eSheath expands from 16F to 18F which facilitates smooth delivery system passage, then returns to a reduced profile once the valve has passed through the sheath



Upcoming Development – 14Fr!

Edwards **SAPIEN 3** Valve

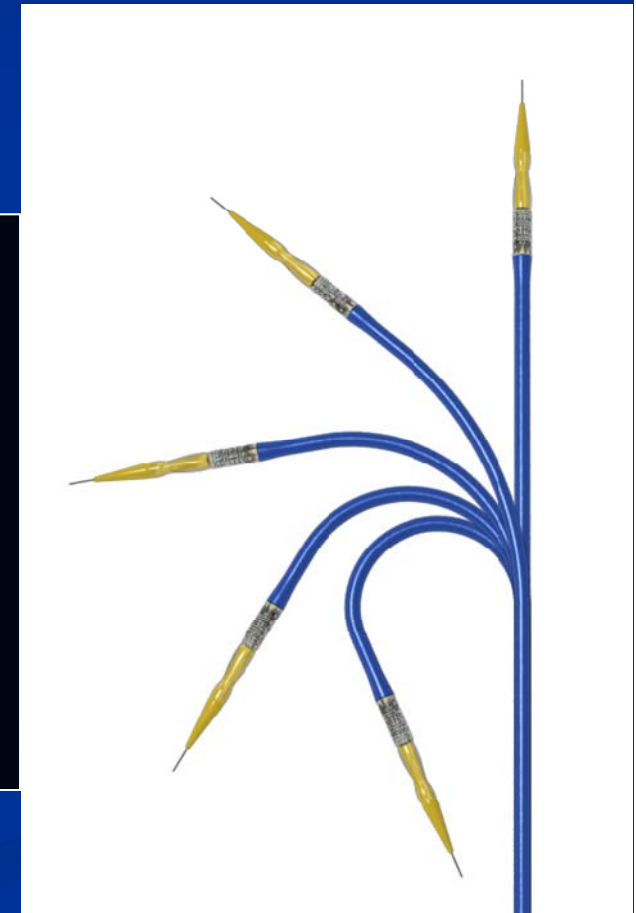
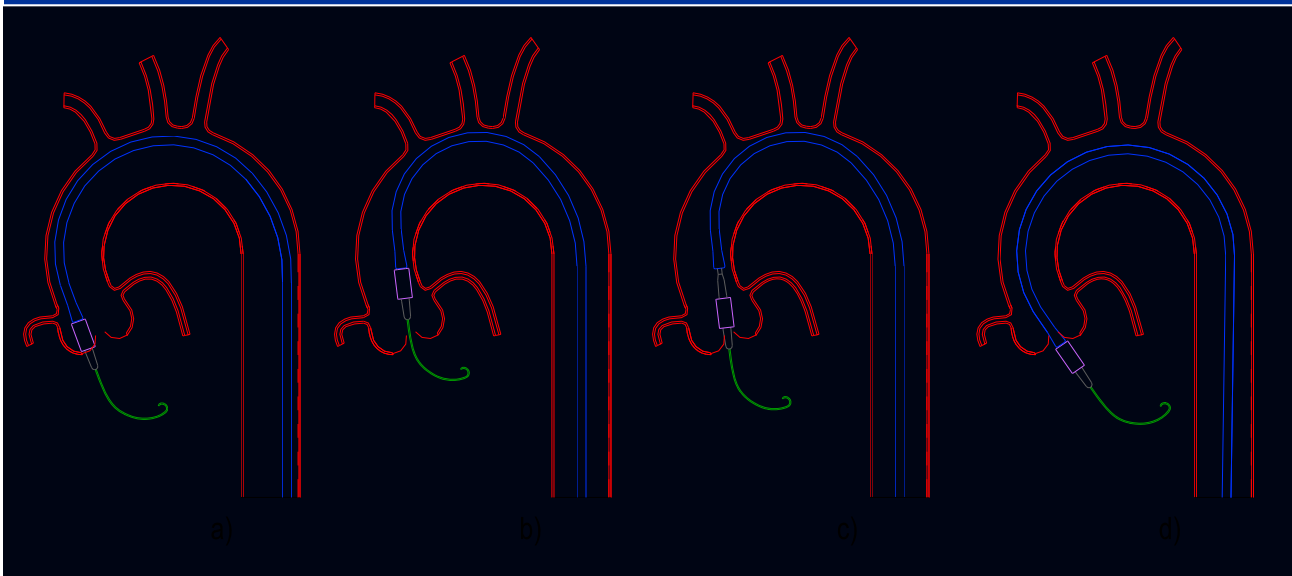


- Lower profile valve delivered through a 14 Fr eSheath
- Discrete valve that anchors in the annulus
- Treated bovine pericardial tissue leaflets
- **Delivered through 14-French eSheath delivery systems**

My wish list

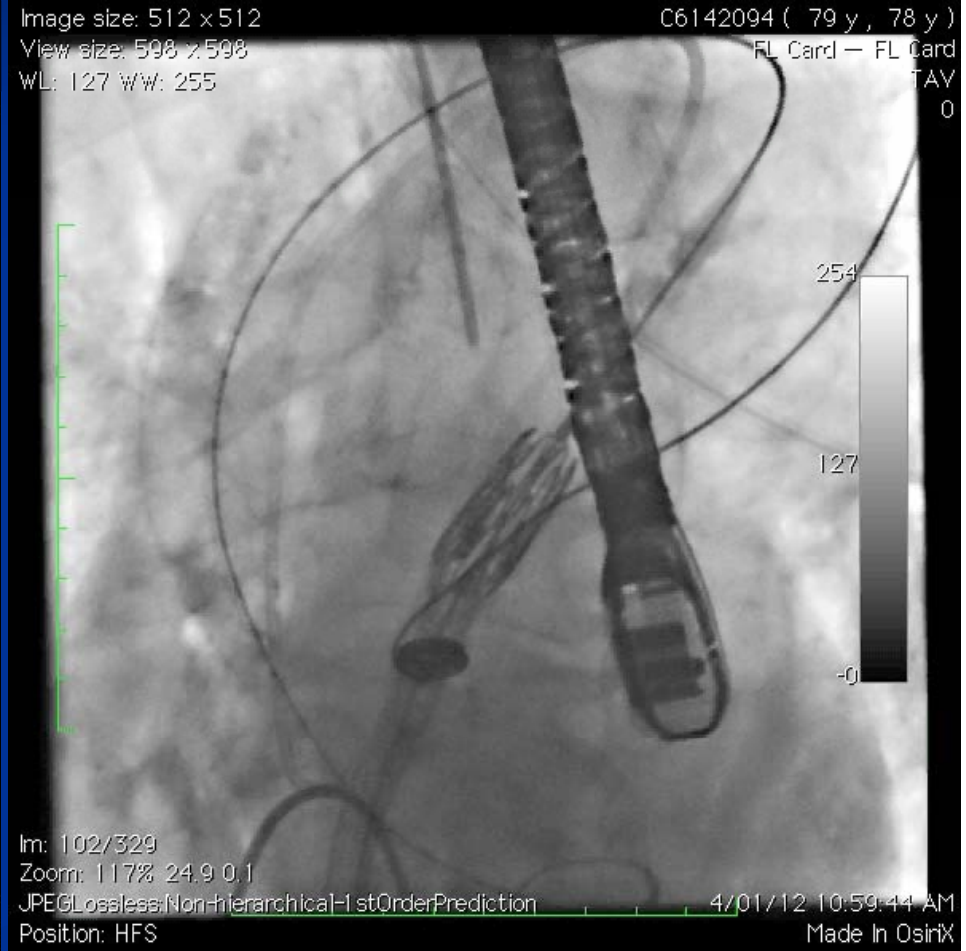
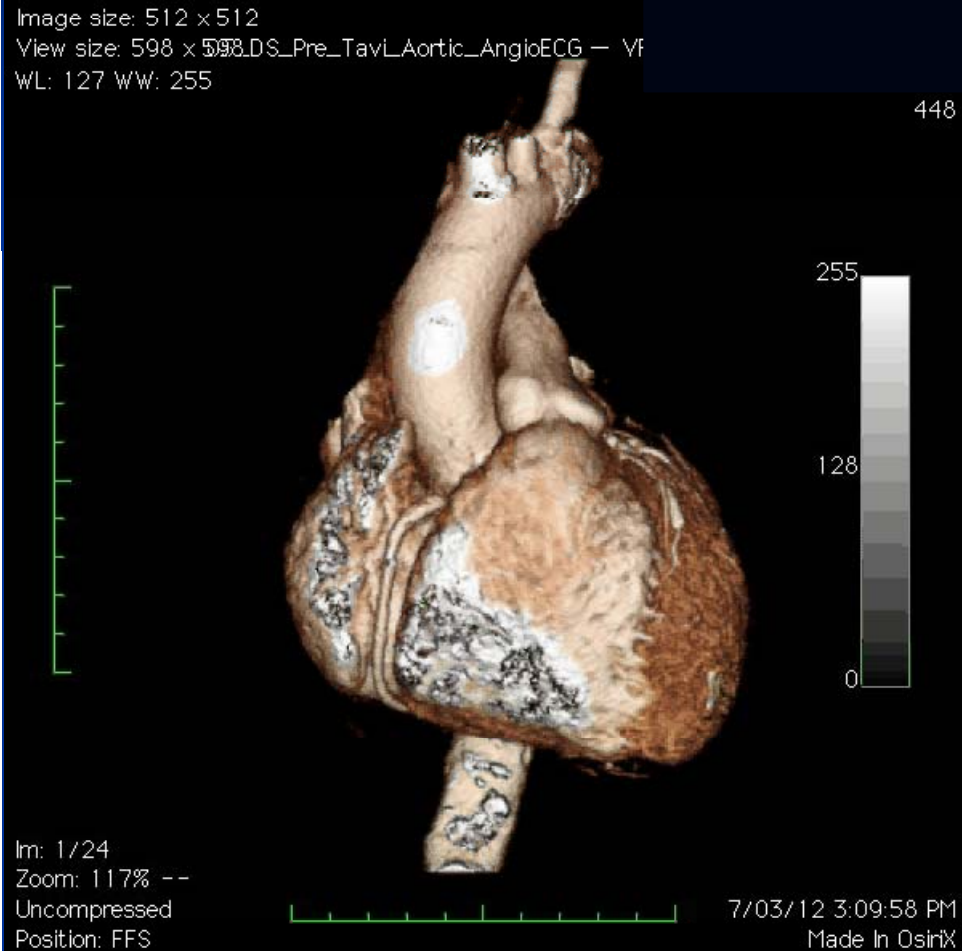
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Crossing Arch and Native Aortic Valve with RetroFlex / NovaFlex Catheter



NovaFlex to Cross Unfolded Aorta

Maximal Flexion and Tension on Wire

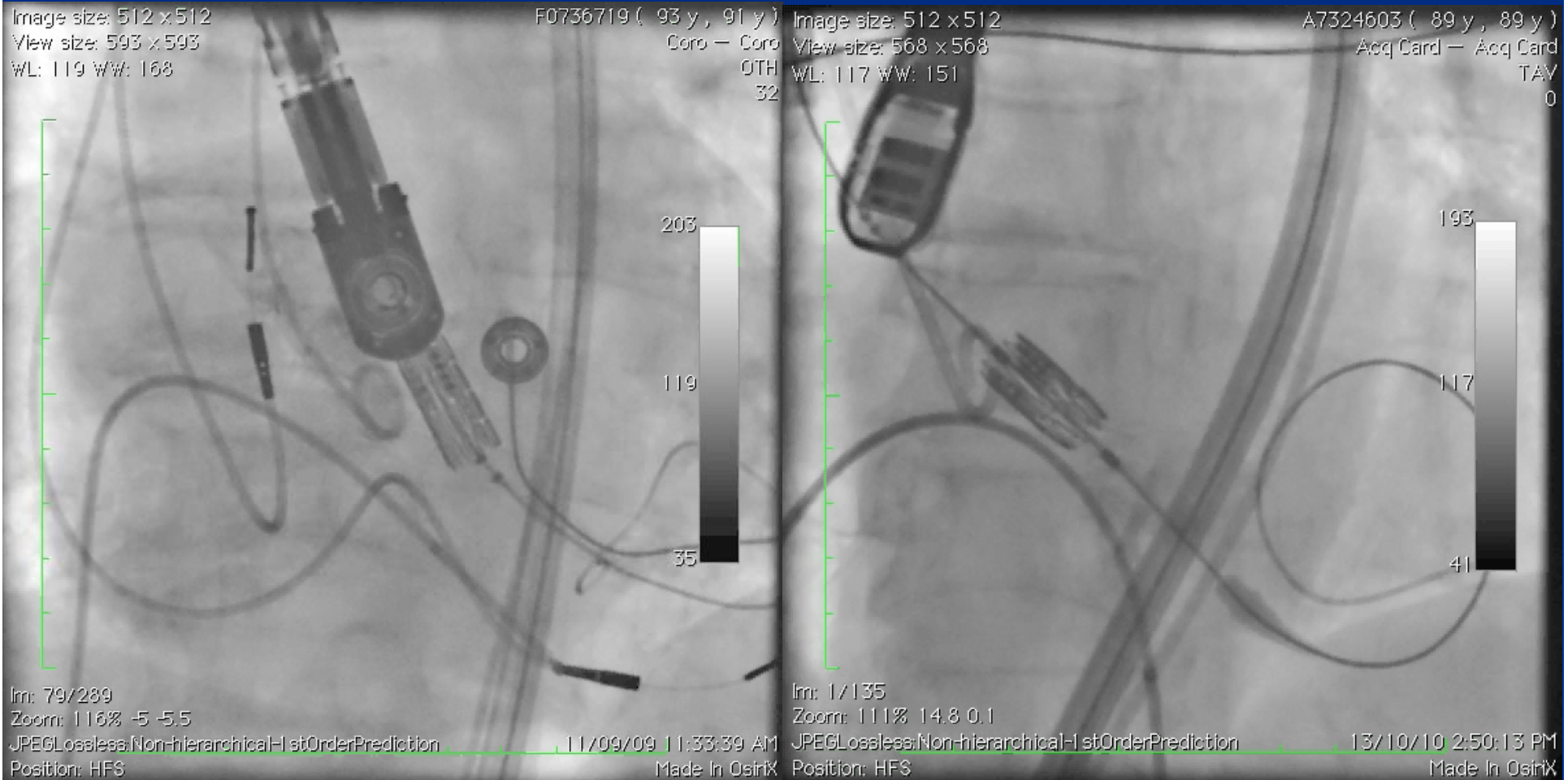


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NovaFlex System

- Easier to achieve co-axial alignment
- Does not move much during valve deployment



RF 1

NF

Valve-in-valve Rescue

- SOURCE (Edwards) – 1.4%
- ADVANCE (CoreValve) – 4%

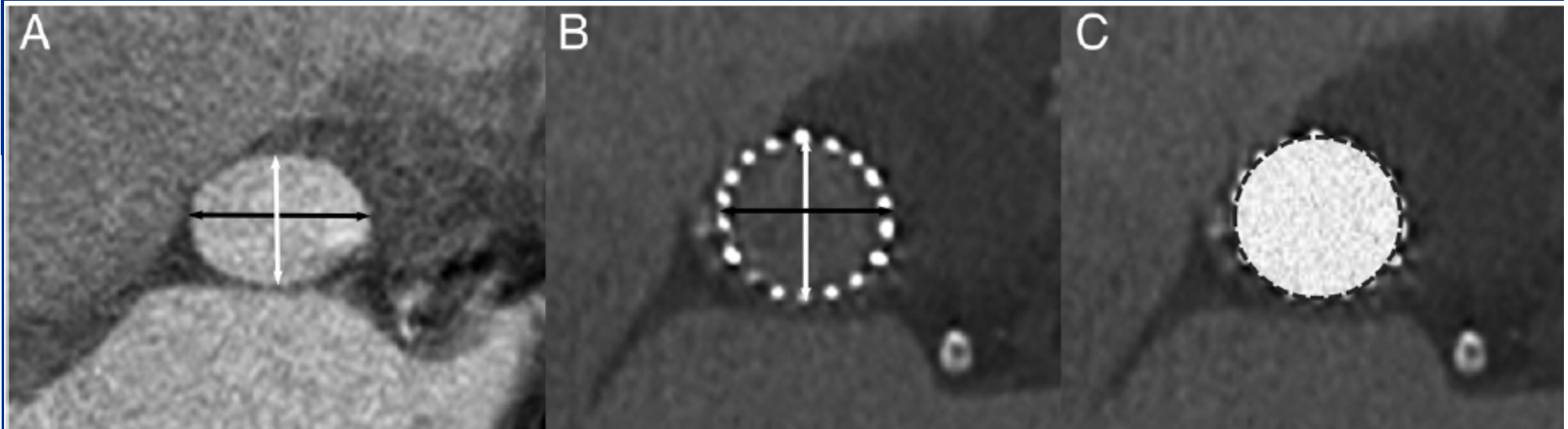
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- Smooth outer surface to pass through aorta -
- Easy transition over arch ✓✓
- Easy transit through valve ✓✓
- **"Self seating"** -
 - **But ease of deployment improved ++**
- Adequate radial strength
- Repositionable if needed
- Retrievable if needed
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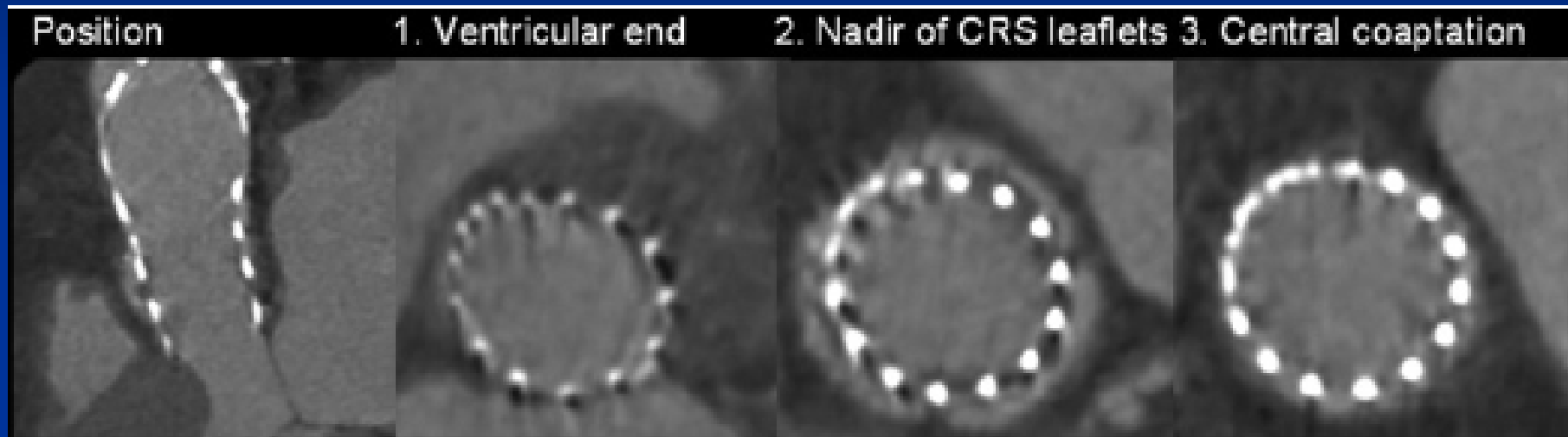
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Geometry of Edwards SAPIEN Post-implant



- Circularity (Min D / Max D > 0.9) – 98%
- Average Expansion – 104%

Geometry of CoreValve Post-implant



- Circularity ($\text{Min D} / \text{Max D} > 0.9$)
 - 0% at ventricular end
 - 17% at leaflet nadie and central co-aptation
- None reach nominal diameter

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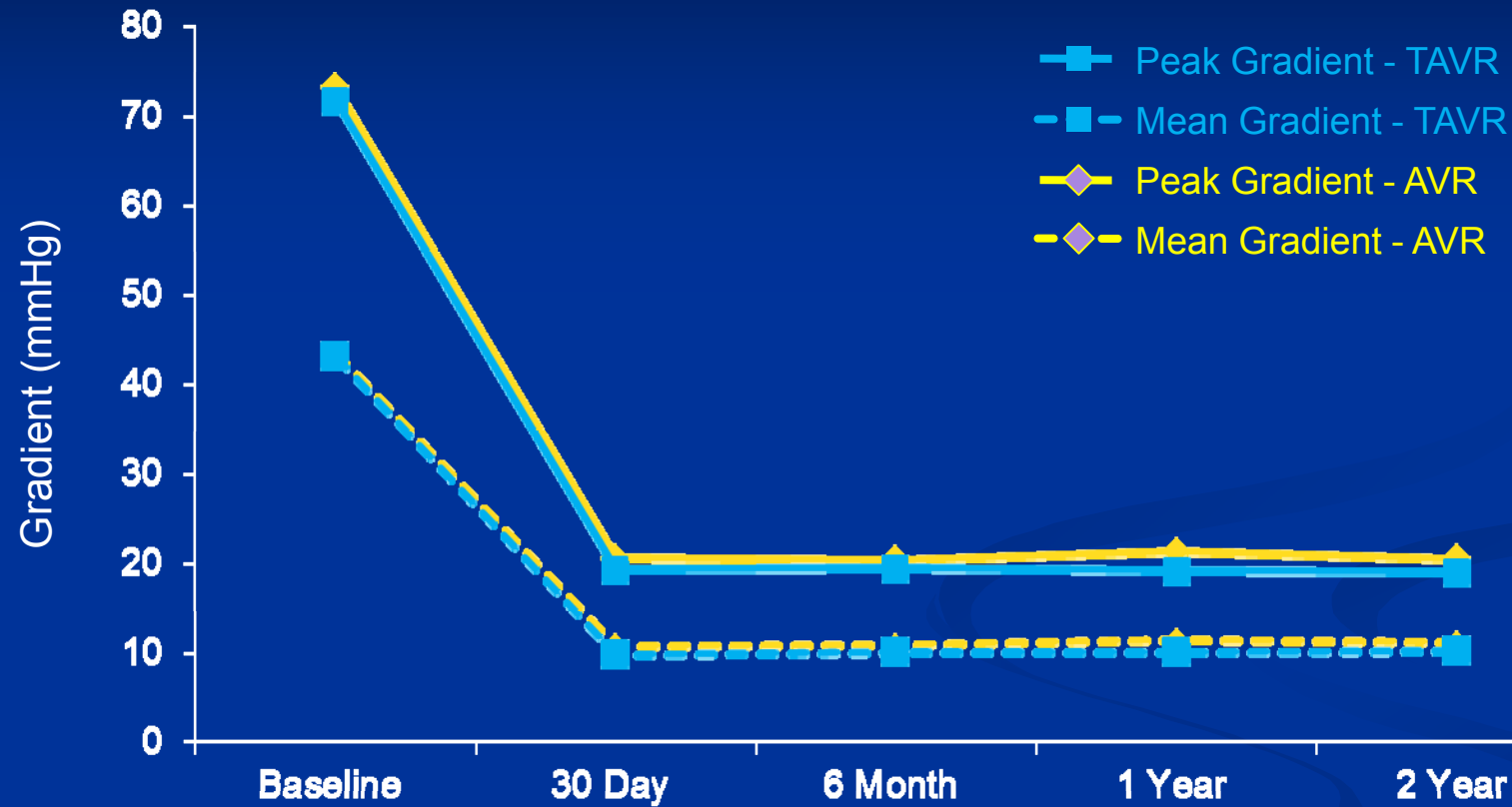
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PARTNER Cohort A

Sustained Haemodynamic Improvement



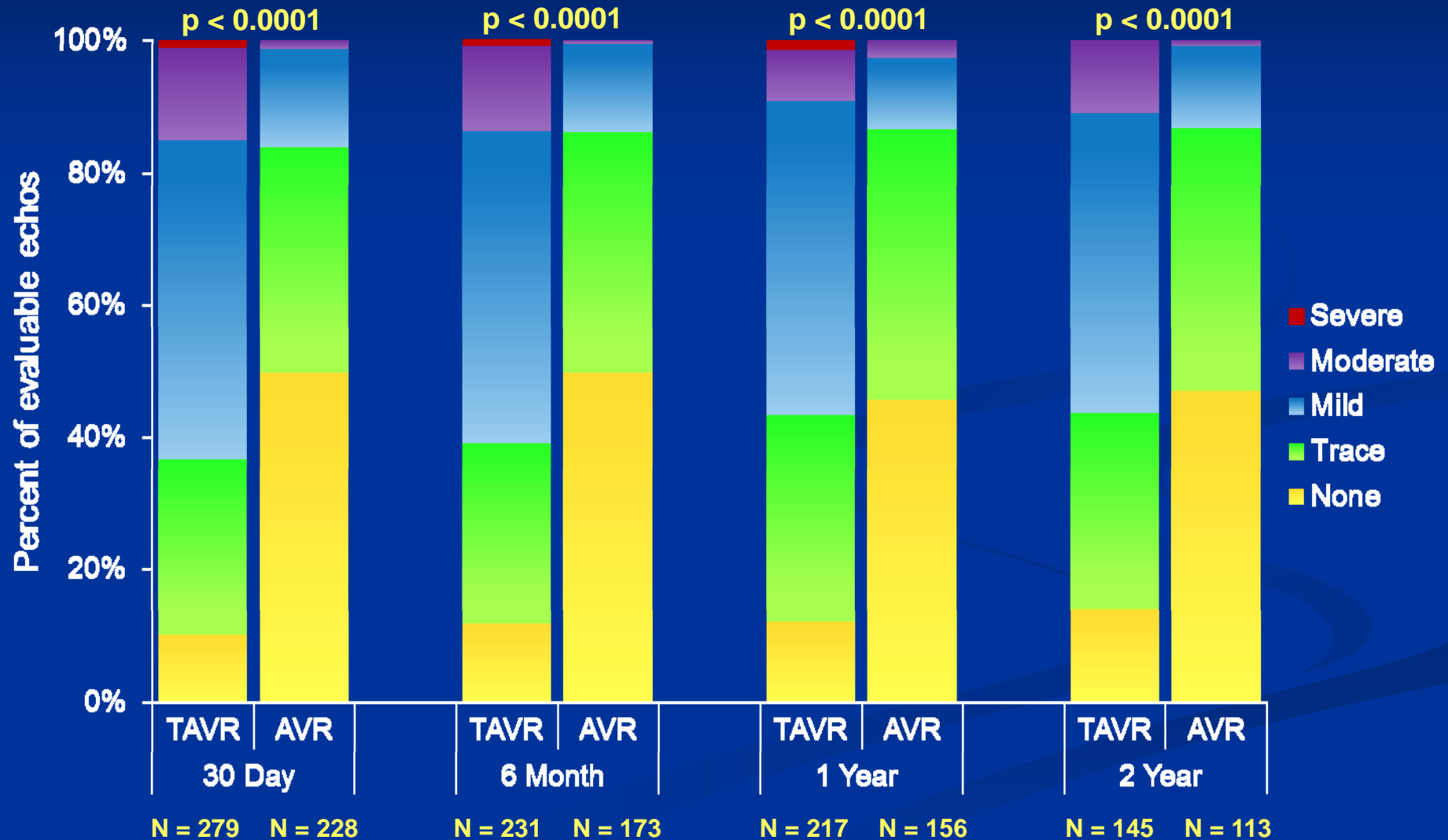
Numbers at Risk

TAVR	307	275	233	218	144
AVR	295	228	168	155	112

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PARTNER COHORT A - Aortic Regurgitation (As Treated)



Aortic Regurgitation

Hospital San Raffaele	All TF (n = 245)	SAPIEN TF (n= 155)	CoreValve (n = 90)	p
AR 3 or 4+; N (%)	12 (4.9%)	6 (3.9%)	6 (6.7%)	.328

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- **Long term durability**

Transcatheter Aortic Valve Implantation

Durability of Clinical and Hemodynamic Outcomes Beyond 3 Years in a Large Patient Cohort

R. Gurvitch, MBBS; D.A. Wood, MD; E.L. Tay, MBBS; J. Leipsic, MD; J. Ye, MD; S.V. Lichtenstein, MD, PhD; C.R. Thompson, MD; R.G. Carere, MD; N. Wijesinghe, MD; F. Nietlispach, MD; R.H. Boone, MD; S. Lauck, RN; A. Cheung, MD; J.G. Webb, MD

- 70 patients who had Edwards SAPIEN valve implant with at least 3 year follow-up
- Median F/up 3.7 years
- Mean gradient increased from 10.0mmHg to 12.7mmHg (p=0.03)
- No structural deterioration or stent fracture

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TAVI – Contemporary Results

	PARTNER B	PARTNER A	SOURCE	Canadian	FRANCE 2	CoreValve Meta- analysis	ADVANC E
N & Valve type	Edwards 179	Edwards 348	Edwards 2307	Edwards 339	Edwards 1145 CoreValve 540	CoreValve 2156	CoreValve 1015
Age	83.1	83.6	80.1	81.8	82.5	81.6	81
Logistic EuroScore	26.4%	29.3%	26.1%	N/A	22.6%	21.3%	19.2%
30 day Mortality	5.0%	3.4%	9.5%	10.4%	9.9%	6.6%	4.5%
30 day Stroke	6.7%	5.5%	2.9%	2.3%	3.8%	2.8%	2.9%
1 year Mortality	30.7%	24.2%	23.5%	24%	24%	17.1%	

TAVI – Contemporary Results

	PARTNE R B	PARTNE R A	SOURCE 1 & 2	Canadian	FRANCE 2	CoreValve Meta- analysis	ADVANC E
N & Valve type	Edwards 179	Edwards 348	Edwards 2307	Edwards 339	Edwards 1145 CoreValve 540	CoreValve 2156	CoreValve 1015
Vascular Cx	16.8%	11.0%	5.7%	13.0%	12.5%	4.2%	10.7%
Bleeding	16.2%	9.3%	3.3%	N/A	18.4%	N/A	13.7%
PPM	3.4%	3.8%	6.9%	4.9%	12.4%	28.7%	26.7%

Conclusion

- Is Edwards balloon expandable valve enough
 - Probably not
- Is Edwards better than CoreValve
 - Yes in terms of PPM

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Same day admit
Local anesthesia
Versed/fentanyl
Radial/fem insertion (7Fr)
4 hr recovery
Home →

